K063710

510(k) Premarket Notification
New Medical Co.,LTD. – Saturn 9000
December 11th, 2006

JUL 16 2007

510 (K) Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92 9 (c)

1. **Submitter:** New Medical Co.,LTD.
4F, No.42, SingZhong Rd., NeiHu District
Taipei 114, Taiwan

Contact Person: Young-Hoon Shin, Ph.D.
R&D Manager
yhshin@newmedical.com.tw
Telephone: +886-2-8791-6268

Date Prepared: December 11th 2006

2. **Device Name:** Saturn 9000

3. **Marketd Device:** new submission

4. **Device Description:** The Saturn 9000 is equipped with a digital detector, X-ray generator interface, and image acquisition workstation. The digital detector is a-Se deposited plat panel detector. The input X-ray photons are absorbed in a-Se layer that creates an electrical charge which is representation of the X-ray input. The charge is read-out by a matrix scan of the array that converts the charges into a modulated electrical signal. X-ray exposure is controlled by switch box, which also controls the acquisition timing of the detector. Saturn 9000 includes acquisition workstation ("AWS") monitor, keyboard and mouse, computer, electronics, and accessory storage. The resultant output signal can be transmitted to remote viewing sites, and/or it can be stored electronically for later viewing. The AWS is used for image acquisition, processing, and display. The AWS can also be used for database management and can send images to archive, review or filming.

5. **Indications for Use:** The Saturn 9000 system generates digital X-ray images that can be used for general X-ray system except mammography. The Saturn 9000 system can

Interface to traditional X-ray generator and get digital X-ray image. The Saturn 9000 is intended to be used in same clinical application as traditional film-screen based general radiography system.

6. **Comparison with Predicate Device**: The Saturn 9000 is of a comparable type and substantially equivalent to solid state X-ray imaging devices. It has the same technological characteristic and is comparable in key safety and effectiveness features. It utilizes similar design, construction, and interface scheme. It has same intended uses and basic operation modes as the predicate device.

7. **Non-clinical Tests**: The performance of the device has been evaluated and has been founded to confirm with applicable medical device performance and safety standards. Based on industrial standard, IEC 62220-1, many technical characteristic values were measured and computed and it is conformed that the device performance is compatible with predicate device.

8. **Clinical Tests**: Concurrence study is preferred for proving the clinical effectiveness of Saturn 9000 system as "X-ray digital image capture device" which is classified as "Class II" device according to the guideline of MED/2.7/R1. StingRay manufactured by INFIMED, Inc is assigned as approved predicate device

9. **Conclusion**: Intended uses and other key features are consistent with previously cleared solid state X-ray imaging devices. The device conforms to applicable medical device safety standards and compliance was verified through independent clinical trial. Saturn 9000 is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Young-Hoon Shin
Director of R&D
New Medical Company, Ltd.
4F, No. 42, SingZhong Road
HEIHU DISTRICT TAIPEI 114
TAIWAN

AUG 23 2013

Re: K063710
Trade/Device Name: Saturn 9000
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 11, 2007
Received: June 11, 2007

Dear Mr. Shin:

This letter corrects our substantially equivalent letter of July 16, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K 063710

Device Name: Saturn 9000

Indications For Use:

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Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CIONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K063710